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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,965	06/20/2006	Ezio Bombardelli	2503-1189	7314

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EXAMINER	
ML, QIUWEN	
ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/563,965	BOMBARDELLI, EZIO	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-10,13 and 14* is/are pending in the application.

4a) Of the above claim(s) *3,6-8 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,9,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment in the reply filed on 10/30/09 is acknowledged, with the cancellation of Claims 5, and 11-12; and newly added claim 14, which is drawn to the elected invention. Claims 1-4, 6-10, 13, and 14 are pending. Claims 3, 6-8, and 10 are withdrawn as they are directed toward a non-elected invention groups or species. **Claims 1, 2, 4, 9, 13, and 14 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

Claim Objections

Claims 1, 2, 4, 9, 13, and 14 are newly objected to because of the following informalities:

Claims 1 and 13 as amended recite "and glucosides thereof in 7 and 3" in line 11; and claim 14 also recites "and glucosides thereof in 7 and 3" in line 14. The phrase "glucosides thereof in 7 and 3 is incomplete and confusing. "7 and 3" of what? Applicant is required to specify the position of the glucosides in a complete sentence.

All other cited claims depend directly or indirectly from objected claims and are, therefore, also, objected for the reasons set forth above.

Claim Rejections –35 USC § 112, 1st New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claim 14 recites "…a combination of vasoactive agents incorporated into a form selected from the group consisting of a cream, a gel, a lotion, and a milk..." in lines 3-5. However, the specification fails to provide any support regarding "lotion". Therefore, it is not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, Applicant had possession of the "lotion" in the invention. Thus, the subject matter of "lotion" is a new matter that needs to be cancelled.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4, 9, and 13 remain rejected, and claim 14 is newly under 35 U.S.C. 103(a) as being unpatentable over Di Pierro (WO 02/098436 A1), in view of Bertini Curri et al (US 5,176,919), and further in view of Smith, III et al (US 2003/0069618).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 6/30/09, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Di Pierro discloses a pharmaceutical and/or cosmetic composition for the treatment of cellulite comprising 0.1-2.5% complex of escin/beta-siterol with phospholipids (the third vasoactive agent, thus overlaps with the claimed range of 0.5-2%), 0.1-2.5% complex of *Gingko biloba* dimeric flavonoids with phospholipids (the second vasoactive agent, thus overlaps with the claimed range of 0.1-1%) etc (page 2, lines 20-28). Di Pierro also teaches that the complex of escin/beta-sitosterol with phospholipids has the same action as escin, but shows a more prolonged release of the active principles and improved bioavailability (page 3, lines 10-13); and the complex of *Gingko biloba* dimeric flavonoids with phospholipids, has the same activity as the dimeric *Gingko biloba* flavones in the free form, but shows a more prolonged release of the active principles and better bioavailability. *Gingko biloba* dimeric flavonoids are extremely potent vasoactive agents due to their inhibitory action on the release of histamine and of the enzyme cAMP phosphodiesterase from mast cells (page 3, liens 13-20). Di Pierro further teaches that the composition of the invention will be formulated in the form of cream, oil, gel, foam, emulsion, milk (page 4, lines 15-20).

Di Pierro does not teach the incorporation of the first vasoactive agent visnadin, or the claimed amount of visnadin into the composition.

Bertini Curri et al teach pharmaceutical and cosmetic compositions comprising extracts of Ammi visnaga and Ammi majus containing visnadine (the same as visnadin) and/or visnadine-like coumarins and flavoncoumarols, or visnadine itself in purified form, for the cosmetic

treatment of defects due to insufficient blood perfusion of the skin and of the subcutaneous adipose tissue, particularly for the treatment of precocious senile involution of the face and neck skin, cellulitis, cutaneous stretch marks, alopecias and similar conditions (col 2, lines 10-25). Bertini Curri et al also teach the composition is a cream, ointment, gel or lotion (claim 5). Bertini Curri et al further teach a gel containing 1% of visnadine as active principle (1 g of visnadine out of a 100 g gel) (thus falls into the claimed range of 0.05-2% for the first vasoactive agent).

Smith, III et al teach that in the condition of cellulite, a reduction in local blood supply to the tissues results from increased pressure on the tissues due to upwards pressure from excess underlying adipose tissue, as well as, from deposition of plaque-like substances that clog the arterioles and venous capillaries. The increased blood perfusion flushes the capillaries and arterioles, resupplying the tissues with needed, newly oxygenated blood, and enhancing lymphatic drainage [0049].

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the a vasoactive agent visnadine from Bertini Curri et al to treat cellulite in Di Pierro since Bertini Curri et al teach visnadine is used for cosmetic treatment of defects due to insufficient blood perfusion and as evidenced by Smith et al, cellulite is due to a reduction in local blood supply and deposition of plaque-like substances that clog the arterioles and venous capillaries. Therefore, one of ordinary skill in the art would have been motivated to use the vasoactive agent visnadine from Bertini Curri et al to let the increased blood perfusion flushes the capillaries and arterioles, and resupplying the cellulite tissues with needed, newly oxygenated blood, and enhancing lymphatic drainage so as to enhance the treatment of cellulite of Di Pierro. It would be obvious for one of the ordinary skill in the art to exclude the

components ethylximeninate, and standardized *Coleus forskolli* extract from Di Pierro, as they are only optional as taught by Di Pierro. Furthermore, a cream, a gel or milk is allowed to contain variety of components with different activities.

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that it is deemed that the prior art product must not be precluded for use as a vasoactive agent. It is deemed that the composition disclosed by Di Pierro and Bertini Curri et al is not precluded for carrying out the intended function of the claims.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that "The combination fails to suggest the unexpected results. The invention described in independent claims 1 and 13 comprises a combination of vasoactive agents consisting of a particular group of vasoactive components. The composition of claim 14 consists of the combination of vasoactive agents recited in claim 1 in one of the forms recited in claim 1" (page 10, 1st paragraph). Applicant also argues that "The Examiner's attention is respectfully directed to the Declaration Under Rule 132 filed on May 30, 2007. The declaration demonstrates the synergistic behavior of a combination of vasoactive ingredients encompassed by the independent claims, and specifically recited dependent claim 9:
• visnadin, •*Ginkgo biloba,* dimeric flavones complexed with phospholipids and • escin beta-

sitosterol complexed with phospholipids. That is, the effect achieved by this combination of ingredients was higher than the sum of the effects exerted by each single ingredient (in identical amounts)" (page 10, 2nd paragraph). Applicant further argues that "Accordingly, even if the ingredients of the claimed composition were individually known from the teachings of DI PIERRO and BERTINI CURRI, as evidenced by SMITH, there was no recognition of the synergistic effect of their combination. Rather, DI PIERRO, suggests a synergistic effect achieved by a different combination of components (e.g., as discussed on page 2, lines 2-11). Thus, one of ordinary skill in the art would not have expected the synergistic activity when used in combination" (page 10, last paragraph bridging page 10).

This is not found persuasive. The Group 5 in Declaration Under Rule 132 filed on May 30, 2007 which showed unexpected result has a different scope than what is being claimed right now. Group 5 contains 0.3% visnadin, 0.4% ginkgo biloba dimeric flavones complexed with phospholipid and 1.0 escin beta-sitosterol complexed with phospholipid. However, none of the claims recites a composition like that, and there is no description in the Specification for a composition like that. Therefore, the unexpected result does not commensurate with what is being claimed.

Applicant argues that "One would have been discouraged from making the combination. DI PIERRO teaches a mixture of ingredients that produces a synergistic effect in the treatment of localized adiposities and cellulite (reduction of cutaneous fat deposits and "orange-peel" skin)" (page 11, 3rd paragraph). Applicant also argues that "However, DI PIERRO discloses this synergistic effect is achieved using a composition different from the claimed invention. Specifically, the synergistic composition according to DI PIERRO includes (as

described at page 2, lines 2-11):• escin/beta-sitosterol complexes with *phospholipids,• Gingko biloba* dimeric flavonoids complexes with phospholipids,• *Centella asiatica* triterpenes complexes with phospholipids, and •ethyl ximeninate, and • *Coleus forskolii* extracts" (page 11, 2nd paragraph from the bottom). Applicant further argues that "The compositions of independent claims 1 and 13 comprise a particular group of vasoactive agents, and the composition of new claim 14 consists of a particular composition form and a particular combination of vasoactive agents. Ethyl ximeninate and *Coleus forskolii* extracts are not required in the claimed combinations, i.e., the claimed combination is consisting of a particular group of vasoactive agents. Accordingly, in order to even approach the claimed invention, one would have been forced to exclude ethyl ximeninate and *Coleus forskolii* extracts, which would have rendered the composition of DI PIERRO unsatisfactory for the intended purpose of achieving the desired synergistic effect. Thus, one of ordinary skill in the art would have been strongly discouraged from separately using the components of DI PIERRO composition, since one would have expected a loss of the synergistic effect" (page 11, last paragraph bridging page 12; page 12, 2nd and 3rd paragraphs).

This is not found persuasive. In Di Pierro reference, DI PIERRO teaches a composition comprising

a) complex of escin/beta-sitosterol with phospholipids.

b) complex of *Gingko biloba* dimeric flavonoids with phospholipids,

c) complex of Centella asiatica triterpenes with phospholipids,

and optionally one or both of:

d) ethylximeninate, and

e) standardized *Coleus forskolli* extract (page 10, 1st paragraph).

Therefore, components d) ethylximeninate, and

e) standardized *Coleus forskolli* extract are only optional, and they are not required for synergistic effect.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QM

/Michele Flood/

Primary Examiner, Art Unit 1655